MAR 2 4 2005

K050536

Summary of Safety and Effectiveness
Quest Diagnostics Immunoassay/TDM Control

1.0 Submitter

Bio-Rad Laboratories
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Date of Summary Preparation

February 24, 2005

2.0 Device Identification

Product Trade Name:	Quest Diagnostics Immunoassay/TDM Control
Common Name:	Multi-Analyte Controls, (Assayed and Unassayed)
Classifications:	Class I
Product Code:	JJY
Regulation Number:	CFR 862.1660

3.0 Device to Which Substantial Equivalence is Claimed

Lyphochek Immunoassay Plus Control
Bio-Rad Laboratories
Irvine, CA 92618
Docket Number: K981532

4.0 Description of Device

Quest Diagnostics Immunoassay/TDM Control is prepared from human serum, with added constituents of human and animal origin, chemicals, and therapeutic drugs. The control is provided in lyophilized form for increased stability.

5.0 Statement of Intended Use

Quest Diagnostics Immunoassay/TDM Control is intended for use as a quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.

6.0 Comparison of the new device with the Predicate Device

Quest Diagnostics Immunoassay/TDM Control claims substantial equivalence to the Lyphochek Immunoassay Plus Control currently in commercial distribution (K981532).

Table 1. Similarities and Differences between new and predicate device.

Characteristics	Quest Diagnostics Immunoassay/TDM Control (New Device)	Bio-Rad Laboratories Lyphochek Immunoassay Plus Control (Predicate Device K981532)
	Similarities	
Intended Use	Quest Diagnostics Immunoassay/TDM Control is intended for use as a quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.	Lyphochek Immunoassay Plus Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.
Form	Lyophilized	Lyophilized
Matrix	Human Serum	Human Serum
Preservatives	Does not Contains preservatives	Does not Contains preservatives
Storage (Unopened)	2°C to 8°C Until expiration date	2°C to 8°C Until expiration date
	Differences	
Reconstituted Vial Claim	7 days at 2 to 8°C with the following exceptions: (1) C-Peptide, Folate and PSA 3 days (2) Gastrin, Free PSA and Intact PTH assay immediately	7 days at 2°C to 8°C with the following exceptions: (1) Folate and PSA 3 days, (2) C-Peptide 1 day, (3) Intact PTH 16 hours, (4) ACTH, Calcitonin, Gastrin and Free PSA assay immediately
After Reconstituting and Freezing	No claims	All analytes 30 days at -10 to -20°C
Analytes	Contains the following analytes: • 17-α-Hydroxyprogesterone • Acetaminophen • Aldosterone • Alpha Fetoprotein (AFP) • Amikacin • Androstenedione • Caffeine • Carbamazepine • CEA • Chloramphenicol • Cortisol • C-Peptide • DHEA Sulfate • Digoxin • Disopyramide • Estradiol • Estriol, Free • Ethosuximide • Ferritin • Folate • FSH • Gastrin • Gentamicin • Homocysteine • HCG • HGH • Immunoglobulin E (IgE) • Insulin • Lidocaine • Lithium • LH • NAPA • PTH, Intact • Phenobarbital • Phenytoin • Primidone • Procainamide • Progesterone • Prolactin • PAP • PSA • PSA, Free • Quinidine • Salicylate • T3, Free • T3, Total • T4, Free • T4, Total • Testosterone • Theophylline • Tobramycin • TSH • Valproic Acid • Vancomycin • Vitamin B12	Contains the following analytes: • 11-Deoxycortisol • 17-α-Hydroxyprogesterone • Acetaminophen • ACTH • Alpha Fetoprotein (AFP) • Amikacin • Aldosterone • Amitriptyline • Androstenedione • Caffeine • Calcitonin • Carbamazepine, Free • Carbamazepine • CEA • Chloramphenicol • Cortisol • C-Peptide • DHEA Sulfate • Digoxin • Disopyramide • Cyclosporine • Desipramine • DHEA • Estradiol • Estriol, Free • Estriol, Total • Estrogens, Total • Ethosuximide • Ferritin • Immunoglobulin E (IgE) • Insulin • Lidocaine • Lithium • LH • NAPA • Netilmicin • Nortriptyline • PTH • Phenobarbital • Phenytoin • Phenytoin, Free • Primidone • Procainamide • Progesterone • Prolactin • PAP • Propanolol • PSA • PSA, Free • Quinidine • Salicylate • T3 Free • T3 Total • T3 Uptake • T4 Free • T4 Total • TCA Screen • Testosterone

Characteristics	Quest Diagnostics Immunoassay/TDM Control (New Device)		Bio-Rad Laboratories Lyphochek Immunoassay Plus Control (Predicate Device K981532)	
	Does not Contains the following analytes:		• Folate	• Testosterone, Free
	• 11-Deoxycortisol	• HCG-Beta Subunit	• Flecainide	• Theophylline
	• Aldosterone	• Imipramine	• FSH	• Tobramycin
	• Amitriptyline	• Netilmicin	• Gastrin	• TSH
	• Calcitonin	• Nortriptyline	• Gentamicin	• Valproic Acid
	• Carbamazepine, Free	• Phenytoin, Free	• hCG and hCG-Beta Subunit	• Valproic Acid, Free
	• Cyclosporine*	• Propanolol	• hGH	• Vancomycin
	• Desipramine	• T3 Uptake	• Imipramine	• Vitamin B12
	• DHEA	• TCA Screen	• 25-Hydroxy Vitamin D	• Immunoglobulin A (IgA)
	• Estriol, Total	• Testosterone, Free	• Angiotensin I	• Immunoglobulin G (IgG)
	• Estrogens, Total	• Valproic Acid, Free	• Fructosamine	• Immunoglobulin M (IgM)
	• Flecainide	• Immunoglobulin A (IgA)	• Glucagon	• Somatomedin-C
	• 25-Hydroxy Vitamin D	• Immunoglobulin G (IgG)	• Iron	• TBG
	• Angiotensin I	• Immunoglobulin M (IgM)	• TIBC	• Thyroglobulin
	• Fructosamine	• Somatomedin-C	Does not Contains the following analytes:	
	• Glucagon	• TBG	• Homocysteine	
	• Iron	• Thyroglobulin		
	• TIBC			

1.0 STATEMENT OF SUPPORTING DATA

Stability studies have been performed to determine the open vial stability and shelf life for the Quest Diagnostics Immunoassay/TDM Control. Product claims are as follows:

- Open vial Stability: 7days when stored tightly capped at 2 to 8°C with the following exceptions: C-Peptide, Folate and PSA are stable for 3 days and Gastrin, Free PSA and Intact PTH should be assayed immediately after reconstitution.

- Shelf Life: 36 months when stored at 2 to 8 °C

All supporting data is retained on file at Bio-Rad Laboratories.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 2 4 2005

Ms. Elizabeth Platt
Regulatory Affairs Manager/ Quality Assurance
Bio-Rad Laboratories, QSD
9500 Jeronimo Road
Irvine, CA 92618-2017

Re: k050536
Trade/Device Name: Quest Diagnostics Immunoassay/TDM Control
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJY
Dated: February 24, 2005
Received: March 2, 2005

Dear Ms. Platt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Jean M. Cooper MS, DVM

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Quest Diagnostics Immunoassay/TDM Control

Indications For Use: Quest Diagnostics Immunoassay/TDM Control is intended for use as a quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in this package insert.

Prescription Use __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K050536